

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6644]

Fiscal Year 2019 Generic Drug Regulatory Science Initiatives; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "FY 2019 Generic Drug Regulatory Science Initiatives."

The purpose of the public workshop is to provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders--industry, academia, patient advocates, professional societies, and other interested parties--as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2020 regulatory science initiatives.

DATES: The public workshop will be held on May 1, 2019, from 8:30 a.m. to 4:30 p.m.

Submit either electronic or written comments on this public workshop by June 1, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C),

Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-6644 for "FY 2019 Generic Drug Regulatory Science Initiatives; Public Workshop; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephanie Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3742, Silver Spring, MD 20993, 240-402-7960, Stephanie.Choi@fda.hhs.gov; or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240-402-7957, Robert.Lionberger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments of 2012 (GDUFA I) (Pub. L. 112-144). GDUFA I was designed to enhance public access to safe, high-quality generic drugs and to modernize the generic drug program. To support this goal, FDA agreed in the GDUFA I commitment letter to work with industry and interested stakeholders on identifying regulatory science initiatives specific to generic drugs for each fiscal year covered by GDUFA I.

In August 2017, GDUFA I was reauthorized until September 2022 through GDUFA II (Pub. L. 115-52). In the GDUFA II commitment letter,¹ FDA agreed to conduct annual public workshops "to solicit input from industry and stakeholders for inclusion in an annual list of GDUFA II [r]egulatory [s]cience initiatives." The public workshop scheduled for May 1, 2019, seeks to fulfill this agreement.

II. Topics for Discussion at the Public Workshop

The purpose of the public workshop is to obtain input from industry and other interested stakeholders on the identification of generic drug regulatory science initiatives for FY 2020.

FDA is particularly interested in receiving input on the following three topics:

1. FY 2019 regulatory science initiatives,² including specific products or actions that FDA should consider as it implements those initiatives, including, for example:
 - a. The value to the generic drug product industry in expanding the Biopharmaceuticals Classification System Class III waivers to include non-Q1/Q2 formulations,

¹ The GDUFA II commitment letter is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf>.

² The FY 2019 regulatory science initiatives are available at <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM626329.pdf>.

- b. Scientific gaps that impact the prediction of the results of fed bioequivalence studies (when the drug product is administered shortly after a meal, as opposed to administration under fasting conditions), and
 - c. Challenges for industry in implementing new analytical or computational methods that arise from regulatory science initiatives.
- 2. Recently approved new drug applications that may pose scientific challenges to the future development of generic drug products referencing those applications.
 - 3. Regulatory science initiatives that FDA should begin to consider in FY 2019, including, for example:
 - a. Scientific challenges in the evaluation of sensitization for transdermal systems and
 - b. The development of alternative approaches to in vivo bioequivalence studies to evaluate product equivalence.

FDA will consider all comments made at this workshop or received through the docket (see ADDRESSES) as it develops its FY 2020 regulatory science initiatives. Information concerning the regulatory science initiatives for generic drugs can be found at <https://www.fda.gov/gdufaregscience>.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please email complete contact information for each attendee--including the attendee's name, title, affiliation, address, email, and telephone number--to GDUFARegulatoryScience@fda.hhs.gov. Please also indicate in the email whether attendance will be by webcast or in person.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by April 1,

2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Stephanie Choi (see FOR FURTHER INFORMATION CONTACT) no later than April 1, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments (and requests to participate in the focused sessions). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 8, 2019. All requests to make oral presentations must be received by the close of registration on April 1, 2019, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to GDUFARegulatoryScience@fda.hhs.gov no later than April 22, 2019, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Please register online by April 1, 2019, 11:59 p.m. Eastern Time to attend the workshop remotely. Please note that remote attendees will not be able to speak or make presentations

during the public comment period or during any other session of the workshop. To join the workshop via the webcast, please go to <https://collaboration.fda.gov/gdufa2019/>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov> or at <https://www.fda.gov/gdufaregscience>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/gdufaregscience>.

Dated: January 16, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019-01067 Filed: 2/4/2019 8:45 am; Publication Date: 2/5/2019]